

## **REMARKS**

Claims 1 to 29 are pending in this application. Claims 1 to 10 and 29 are allowed and claims 11 to 28 are rejected. Applicants are herein amending claim 9. Applicants request reconsideration of the rejections in light of the amendments and following remarks.

### **Summary of Rejections**

Claims 11 to 28 are rejected as follows:

- claims 11 to 28 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly non-enabled;
- claims 23 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite;
- claims 11 to 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 27 to 55 of US 10/820,215; and
- claims 11 to 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1 to 95 and 104 to 108 of US 10/961,871.

### **Amendments to Claims**

Applicants are herein amending claim 9 to correct an obvious typographical error, *i.e.*, where one set of “{ }” is missing in the name. Applicants submit that no new matter is introduced by the amendments to the claims and is fully supported by the specification is originally filed, including original Example 3 that provides mass spectrometry data.

### **Rejection under 35 U.S.C. § 112, first paragraph**

Claims 11 to 28 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly non-enabled. Applicants traverse the rejection.

More specifically, the Office alleges that claim 11 to 28 are not enabled because the specification fails to describe “how to use” the compositions of the invention for treating and preventing “any and all diseases and/or conditions associated with excitatory amino acid receptor activity” (page 3). Further, the Office alleges that the claims are not enabled because they encompass the “prevention” of disorders. (*Id.*)

With respect to the prevention of disorders, no evidence has been presented that there is any reason to doubt that a skilled artisan would doubt that the compounds of the invention would not be useful in preventing opiate tolerance, especially in light of the fact that NMDA receptor antagonists are known to prevent the opiate analgesia tolerance. See, for example, the Trujillo abstract (enclosed). Medical professionals have means to measure tolerance to opiate analgesia and would have no difficulty administering the compounds of the invention to effect the desired result, *i.e.*, prevention of the tolerance. No other evidence has been presented that establishes that a skilled artisan would doubt the use of the compounds of the invention, which are NMDA receptor antagonists, would not be useful in the treatment of the listed diseases and conditions.

Applicants submit that the method of treatment claims meet the enablement requirement under 35 U.S.C. § 112, first paragraph. With the exception of cerebral ischemia, it appears that the Office is challenging that there is a correlation between antagonists of the NMDA receptor and the treatment of the various diseases and conditions claimed. As applicants explained on page 14, line 8 to page 15, line 11, the present invention provides methods for treating conditions associated with glutamate abnormalities, *i.e.*, conditions produced by a disease or a disorder in which glutamate, typically in increased amounts, is implicated as a contributing factor. The Office has provided no evidence that any of the listed conditions would not be expected to be treated by the compounds of the invention. While the Office asserts that the methods includes diseases and/or conditions “not even known at this time,” each of the method claims names specific conditions and does not, in fact, claim “all diseases and/or conditions associated with excitatory amino acid receptor activity,” as suggested on page 3 of the Office Action.

Applicants are submitting herewith a number of review articles that show that there is recognized correlation between antagonism at the NMDA receptors and the specified diseases and conditions set forth in the claims:

- Wood PL.  
The NMDA receptor complex: a long and winding road to therapeutics.  
*IDrugs*. 2005 Mar;8(3):229-35. Review.
- Heresco-Levy U.  
Glutamatergic neurotransmission modulators as emerging new drugs for schizophrenia.  
*Expert Opin Emerg Drugs*. 2005 Nov;10(4):827-44. Review.
- Bergink V, van Megen HJ, Westenberg HG.  
Glutamate and anxiety.  
*Eur Neuropsychopharmacol*. 2004 May;14(3):175-83. Review.
- Parsons CG.  
NMDA receptors as targets for drug action in neuropathic pain.  
*Eur J Pharmacol*. 2001 Oct 19;429(1-3):71-8. Review.
- Brown DG, Krupp JJ.  
N-methyl-D-aspartate receptor (NMDA) antagonists as potential pain therapeutics.  
*Curr Top Med Chem*. 2006;6(8):749-70
- McCulloch J.  
Excitatory amino acid antagonists and their potential for the treatment of ischaemic brain damage in man.  
*Br J Clin Pharmacol*. 1992 Aug;34(2):106-14. Review.

Accordingly, applicants submit that claims 11 to 28 meet the enablement requirement under 35 U.S.C. § 112, second paragraph, and therefore request withdrawal of the rejection.

**Rejection under 35 U.S.C. § 112, second paragraph**

Claims 23 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicants traverse the rejection.

More specifically, claims 23 and 24 are rejected for using the phrase “pain relieving agent.” Applicants traverse the rejection because a skilled artisan would have no difficulty understanding the meaning of the phrase. Furthermore, on page 19, lines 27 to page 21, line 21, applicants have provided numerous specific examples of pain relieving agents, leaving no doubt with the skilled artisan to the metes and bounds of the invention with respect to the pain relieving agents.

Applicants submit that claims 23 and 24 meet the definiteness requirement under 35 U.S.C. § 112, second paragraph, and therefore request withdrawal of the rejection.

**Obviousness-type Double Patenting Rejections**

Claims 11 to 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 27 to 55 of US 10/820,215. Also, claims 11 to 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1 to 95 and 104 to 108 of US 10/961,871.

Applicants request that these provisional rejections be held in abeyance until the identification of otherwise allowable subject matter in claims 11 to 28.

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**PATENT**

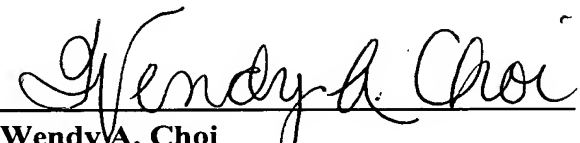
**Conclusions**

Applicants request:

- (1) entry of the amendments to the claims;
- (2) reconsideration and withdrawal of the rejections of the claims 11 to 28; and
- (3) allowance of claims 1 to 29.

If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (404) 459-5642.

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